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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,421	05/17/2006	Jan Clair Nielsen	NIELSEN6A	5536

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,421	NIELSEN, JAN CLAIR	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-9,11,13-15,43,45,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,6-9,11,13-16,18-20,22-26,29,31,32,34,35,37,38,40-43,45,48-52,55,58,59,63-66,68-76,79-82,84-88,90-95 and 98-100.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 16,18-20,22-26,29,31,32,34,35,37,38,40-42,50-52,55,58,59,63-66,68-76,79-82,84-88,90-95 and 98-100.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 9/23/2008 is acknowledged. The traversal is on the ground(s) that PCT unity rules apply, and that, while the basis for the rejection is *a posteriori* lack of unity because Viljakainen *et al.* anticipates claim 1, Viljakainen does not anticipate claim 1. Applicant provides numerous reasons to show that Viljakainen does not anticipate claim 1.

This is not found persuasive because the basis of the rejection was not that Viljakainen anticipated claim 1. The examiner has not asserted that claim 1 is anticipated by Viljakainen and there is no requirement that claim 1 be anticipated for there to be a lack of unity. Under the PCT rules, there must be a special technical feature that links each of the groups. As set forth previously, in the instant claims, the only feature that links all of the groups is a microbial organism that is capable of fermenting at least one fermentable compound. This is the feature that is disclosed in Viljakainen. Therefore, as there is no technical feature linking the inventions that constitutes a special technical feature as defined by PCT Rule 13.2, restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2, 4, 6-9, 11, 13-16, 18-20, 22-26, 29, 31-32, 34-35, 37-38, 40-43, 45, 48-52, 55, 58-59, 63-66, 68-76, 79-82, 84-88, 90-95, and 98-100 are pending. Claims 16, 18-20, 22-26, 29, 31-32, 34-35, 37-38, 40-42, 50-52, 55, 58-59, 63-66, 68-76, 79-82, 84-88, 90-95, and 98-100 are withdrawn as being drawn to nonelected inventions. Claims 1-2, 4, 6-9, 11, 13-15, 43, 45, and 48-49 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 8/28/2006 has been considered. An initialed copy is enclosed.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 11-14.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The use of the trademark TWEEN has been noted in this application on pages 42-44. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that the cited occurrence of improper use is only exemplary and applicant should review the specification to correct any other use of trademarks.

Claim Objections

Claim 1 is objected to because of the following informalities: Each claim should end with a period. Claim 1 lacks a period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4, 6-9, 11, 13-15, 43, 45, and 48-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The instant claims are drawn to an isolated and purified microbial organism that is capable of fermenting malic acid to lactic acid, and which, when placed ina medium containing a predetermined amount of citric acid is only capable of degrading at the most 80% or said citric acid. Said organisms must have at least one of the following two characteristics when said microbial organism in a frozen or freeze dried state is added directly into a fermented fruit juice: i) a survival rate which is at least 1% after two days at 23° C in a fermented sterile fruit juice with a pH of less than 4 and comprising at least 12 vol % ethanol; ii) a survival rate which is at least 70% after two days at 17° C in a fermented sterile fruit juice with a pH of less than 4 comprising at least 13.9 vol % ethanol (claim 1). Additional claims further limit the organism to *Oenococcus oeni* (claim 2); wherein the organism has a survival rate which is at least 10% after two days at 23° C in a wine prepared by yeasting a sterile grape fruit juice without added sulphite, said wine having an ethanol content of 12.0 vol %, pH 3.4, below 5 g/L residual sugar, 3.3 g/L of malic acid, and 450 mg/L of citric acid (claim 4); wherein the organism has a survival rate which is in the range of 70% to 100% after two days at 18° C in a wine prepared with 30 ppm SO_2 added before the alcoholic fermentation, said wine having an ethanol content of 13.8 vol %, pH 3.5, 1.3 g/L malic acid, and 340 mg/L of citric acid (claim 6); wherein the organism has a survival rate which is at least 80% after two days at 17° C in a wine prepared without SO_2 added, said wine having an ethanol content of 13.9 vol %, pH 3.6, 1.7 g/L malic acid, and 320 mg/L of citric acid (claim 7); wherein said microbial organism when placed in a liquid composition comprising a predetermined amount of malic acid is capable of degrading at least 90% of said malic acid (claim 8); wherein said microbial organism is only capable of degrading at the most 50% of said citric acid (claim 9); wherein said microbial organism reduces the citric acid content by less than 50% within 50 days, when added directly in a frozen or freeze dried state to a fermented fruit juice at a concentration of CFUs in the range of $1x10^6$ to $5x10^7$ per ml,

wherein said fermented fruit juice is prepared by yeasting a sterile fruit juice without added sulphite resulting in a fermented fruit juice having an ethanol content of 12.0 vol %, pH 3.4, below 5 g/L residual sugar, 3.3 g/L of malic acid, and 450 mg/L of citric acid (claim 11); wherein said organism is resistant to bacteriophages (claim 13); wherein said organism retains its characteristics during propagation and concentration (claim 14); wherein said organism is selected from the group consisting of strains deposited under the accession numbers DSM 15569, DSM 15570, and DSM 15571 (claim 15); and to a concentrate of said organism which has been propagated in an adaptation medium comprising at least 6% sugar (claim 45) or at least 3% glucose and at least 3% fructose (claim 48); and wherein said organism has been propagated in said adaptation medium for at least 12 hours.

The specification discloses a list of bacteria that can be mutagenized and then selected in order to obtain a strain that meets the limitations of the claims. Strains DSM 15569, 15570, and 15571 are described as meeting the limitations of the claims. Applicant has not described any other microbial organism which does so. However, there is no correlation between the required function (i.e. the required characteristics) and the structure of the product (the microbial organism). Applicant has not described what organisms would have the characteristics required by the claims.

Therefore, the specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid and/or protein itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

It is noted that, while DSM 15569, 15570, and 15571 are described as meeting the limitations of the claims, they do not actually appear to do so. Example 2 shows that unless DSM 15571 is cultured under specific conditions prior to freezing, it will not have the required survival rate. While example 4 shows that DSM 15569, 15570, and 15571 are capable of the required survival rate, based on the results of example 2, one would expect that specific conditions prior to freezing would be required for each of these organisms. However, the claims do not include any of these growth conditions, and the organism itself does not have the required characteristics.

All applicant has provided in the specification is a means for isolating the organism of the claims, and there is no description of an actual organism that meets the limitations. Because possession of the invention, rather than a means for obtaining it is required, the claims do not meet the written description requirements.

Furthermore, the claims require an organism which “when placed in a medium containing a predetermined amount of citric acid is only capable of degrading at the most 80% of said citric acid.” Unless an organism was completely unable to degrade citric acid, it is not clear how one could limit the organism to degrading less than 80% of some unknown amount of citric acid. If the “predetermined amount” of citric acid was extremely high (100 kg per L, for example), it seems likely that the organism would be unable to degrade more than 80%, but if the amount were very low (0.001 g per L, for example) the organism would be able to degrade all of it. Claim 9 has a similar limitation where the reduction in citric acid must be less than 50% within 50 days.

Claim 8 requires that "said microbial organism when placed in a liquid composition comprising a predetermined amount of malic acid is capable of degrading at least 90% of said malic acid." The claim encompasses malic acid in any amount. If the "predetermined amount" is 5 tons per liter, the organism must be able to degrade 90% of it and applicant has not described any organism that has this capability.

Claim 13 requires that the organism be resistant to bacteriophages. The specification lacks any showing that any specific strain is resistant to bacteriophages and has shown no way to make any organism resistant to bacteriophages. As there are bacteriophages that infect practically every bacterial species, the skilled artisan would not expect the organisms disclosed in the specification to be resistant to bacteriophages.

Claim 14 requires that the organism retain its characteristics during propagation and concentration. The specification defines "retaining its characteristics" as retaining its capability of survival and of degrading malic and/or citric acid. The specification does not describe any organism that meets these limitations. As shown in example 2, specific growth conditions are required for the DSM 15569, 15570, and 15571 to survive direct inoculation and it would seem a change in growth conditions alters this characteristic. Furthermore, applicant has shown no means by which one could prevent mutation from altering the organisms characteristics. As such, there is no description of an organism meeting the limitations of this claim.

Therefore, applicant has not demonstrated possession of the claimed genus of microbial organisms and has not shown any organism that meets the limitations of the claims.

Claim 15 is rejected under 35 U.S.C.§112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the organisms with the designations DSM 15569, DSM 15570, and DSM 15571 are required to practice the claimed invention. As such they must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the organisms.

The process disclosed in the specification does not appear to be repeatable and it is not clear that the claimed method will work with commonly available material per se and it is not apparent if the organisms are readily available to the public. It is noted that Applicants have referred to a deposit of the organisms, but there is no indication in the specification as to public availability. The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (**37 CFR 1.808(b))**, that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, **that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.** As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite because the parent claim requires the organism to have at least one of two defined characteristics; however, claim 4 requires "the characteristic" to be a characteristic that is not found in the parent claim and is not encompassed by the parent claim.

Claim 6 is vague and indefinite because the parent claim requires the organism to have at least one of two defined characteristics; however, claim 4 requires "the characteristic" to be a characteristic that is not found in the parent claim and is not encompassed by the parent claim.

Claim 7 is vague and indefinite because the parent claim requires the organism to have at least one of two defined characteristics; however, claim 4 requires "the characteristic" to be a characteristic that is not found in the parent claim and is not encompassed by the parent claim.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645
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